



DEPARTMENT OF COMMERCE

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APPLICATION NUMBER FILING DATE FIRST NAMED APPLICANT ATTY, DOCKET NO. 08/745,509 11/12/96 FELD М MIT-6186Z EXAMENER 33M1/0128 THOMAS O HOOVER HAMILTON BROOK SMITH AND REYNOLDS PAPER NUMBER TWO MILITIA DRIVE LEXINGTON MA 02173-4799 3305

| | DATE MAILED: 01/28/98 |
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| This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS | |
| | |
| OFFICE ACTION SUMMARY | |
| Responsive to communication(s) filed on 9-18-97 | |
| This action is FINAL. | |
| Since this application is in condition for allowance except for formal matters, accordance with the practice under <i>Ex parte Quayle</i> , 1935 D.C. 11; 453 O.G. | prosecution as to the merits is closed in |
| A shortened statutory period for response to this action is set to expire whichever is longer, from the mailing date of this communication. Failure to response the application to become abandoned. (35 U.S.C. § 133). Extensions of time math. 1.136(a). | month(s), or thirty days, and within the period for response will cause by be obtained under the provisions of 37 CFR |
| Disposition of Claims / | |
| (Claim(s) 15-34 | |
| | |
| Claim(s) | |
| Claim(s) 13 39 | is/are rejected |
| Claim(s) | is/are objected to. |
| Claim(s) | are subject to restriction or election requirement. |
| Application Papers | |
| See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. | |
| The drawing(s) filed onis/are | |
| The proposed drawing correction, filed on | |
| The specification is objected to by the Examiner. | is approved disapproved. |
| The oath or declaration is objected to by the Examiner. | |
| Priority under 35 U.S.C. § 119 | |
| Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119 | (a)-(d). |
| ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority docu | ments have been |
| received. | |
| received in Application No. (Series Code/Serial Number) | |
| received in this national stage application from the International Bureau (F | POT Pula 47 0(-)) |
| *Certified copies not received: | C1 nule 17.2(a)). |
| Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 11 | 9(6) |
| Attachment(s) | 5(e) . |
| Notice of Reference Cited, PTO-892 | |
| Information Disclosure Statement(s), PTO-1449, Paper No(s). | |
| Interview Summary, PTO-413 | |
| Notice of Draftperson's Patent Drawing Review, PTO-948 | |
| Notice of Informal Patent Application, PTO-152 | S |
| • | |
| -SEE OFFICE ACTION ON THE FOLLOW | VING PAGES |



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Drawings

The drawings are objected to because the in figure 1, box 80 should be labeled visible light source. FPA 140 is not seen in figure 4 as disclosed. Correction is required.

Claim Rejections - 35 USC § 112

Claims 15-34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 15, it is unclear as to what structure is defined by the term "computer memory device". Claim 16 is incomplete in that it fails to positively set forth a connection between the additional optical fiber and the structure previously set forth. Claim 17 is incomplete in that it fails to positively set forth any connection between the broadband light source and the visible image. In claim 22, it is unclear as to what structure is defined by the term "electronic memory". Claim 23 is incomplete in that it fails to positively set forth a connection between the additional optical fiber and the structure previously set forth. Claim 24 is incomplete in that it fails to positively set forth any connection between the broadband light source and the visible image. The use of alternative language renders claim 29 vague and indefinite. Claim 30 is vague and indefinite in that it is unclear as to whether the laser source is in addition to the radiation source previously set forth. Claim 31 is vague and indefinite in that it fails to positively set forth an active step in the method.

Claims 15-19,29,30,32-34 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. An acousto-optical filter or equivalent filter means critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. *In re Mayhew*, 527 F.2d 1229, 188





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USPQ 356 (CCPA 1976). Applicant fails to disclose how the system would properly operate without the use of a filter positioned to receive the light reflected from the body before it passes to the FPA sensor.

Claims 29-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to disclose a method of endoscopic imaing using a sensor array that senses endogenous fluorescence. The disclosed method senses Raman scattered light.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-17,19-24,26-34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Alfano et al (5,293,872) in view of Lewis et al and Ito or Nagasaki et al. Alfano et al disclose the basic teaching of using a Raman endoscope as a diagnostic tool in examining tissue in vivo. Alfano et al discloses the use of a Nd:YAG laser to excite the tissue. Alfano et al also disclose the use of a broad band light source in order to provide a visible image of the tissue. Lewis et al disclose a spectroscopic imaging device that includes an acousto-optic tunable filter and a focal plane array detector. The focal plane array detector is cooled with liquid nitrogen. The invention of Lewis et al relates to non-invasively collecting images at multiple discreet wavelengths in the visible, infrared or near-infrared region. The device of Lewis et al





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is applicable to biological materials. Lewis et al disclose forming a plurality of images at different infrared wavelengths as seen in column 12. Lewis et al specifically refers to the use of the spectroscopic imaging device in a microscope but states in column 16 that the invention can be applied to other traditional absorption or emission spectroscopic approaches. Therefore, it would have been obvious to one skilled in the art to have modified Alfano et al such that the detector used is a focal plane array for the advantages disclosed by Lewis et al such as improved spectral and spatial resolution. Furthermore, it should be noted that it is a well known expedient in the art to place the imaging device at the distal end of the endoscope rather than using an optical fiber to transmit the detected radiation to an image sensor. Examples of such is shown in Ito and Nagasaki et al. Ito and Nagasaki et al also disclose the use of a filter in front of the image sensor to filter out undesired wavelengths. It would have been obvious to one skilled in the art to have further modified Alfano et al such that the focal plane array sensor is placed at the distal end of the endoscope. The advantage of such is to prevent the quality of pictures from deteriorating due to the breaking of optical fibers.

Claims 18,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al (5,293,872) in view of Lewis et al and Ito or Nagasaki et al as applied to claim 15 above, and further in view of Sekiguchi. Sekiguchi discloses an endoscope that provides both a visible image and an image that provide information regarding tissue properties. The images are displayed simultaneously by a processing unit. Therefore, the system provides means for comparing the images. It would have been obvious to one skilled in the art that the images displayed by Alfano et al are simultaneously displayed such that they can be compared. Such comparison provides a more enhanced diagnostic evaluation tool.





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Conclusion

Applicant's arguments filed 9/18/97 have been fully considered but they are not persuasive. Applicant fails to disclose how the system would properly operate without the use of a filter positioned to receive the light reflected from the body before it passes to the FPA sensor. In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smitn whose telephone number is (703) 308-3063.

RUTH S. SMITH
PRIMARY EXAMINER
ART UNIT 3305

RSS January 25, 1998